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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/215,435	12/17/98	EDWARDS J	GENSET.019A

EXAMINER	
BUGAISKY, G	
ART UNIT	**PAPER NUMBER**
1653	20

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DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad mark

Office Action Summary

Application No.	Applicant(s)
09/215,435	Dumas Milnes Edwards et al.
Examiner	**Group Art Unit**
Gabriele E. Bugalsky	1653

☒ Responsive to communication(s) filed on *Dec 28, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *9-12, 15, 17, 19, and 21-45* is/are pending in the applicat

Of the above, claim(s) *9-12, 15, 17, 19, and 22-45* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The request to amend the drawing (figure 9) has been received and reviewed by the USPTO Drafting Division. A PTO 948 detailing the changes necessary is attached.

It is indicated in the response that several exhibits have been submitted with the amendment. (see e.g., page 10, line 9). No such exhibits were with the pplication when received by the examiner.

The response filed 28 Dec 2000 has been received and entered. Claims 1-8, 13, 14, 16, 18, and 19 have been canceled in favor of claims 21-45. In the prior Office Action, it was indicated that the following sequences were elected:

Sequence	Priority Date
SEQ ID NO:66	8/10/98
SEQ ID NO:71	8/10/98
SEQ ID NO:76	12/17/97
SEQ ID NO:78	8/10/98
SEQ ID NO:113	2/9/98
SEQ ID NO:116	2/9/98
SEQ ID NO:117	4/13/98
SEQ ID NO:118	4/13/98
SEQ ID NO:123	2/9/98
SEQ ID NO:124	4/13/98

In regard to newly submitted claims 22-45 refer to and recite sequences not originally elected nor are they directed specifically to clones of cells containing only the elected polynucleotides. The current recitation of sequences 167, 177, 179, and 225 and of clones:

Clone
47-14-1-C3-CL0_5
51-11-3-D5-CL1_3
51-15-4-A12-CL11_3
78-8-3-E6-CL0_1

is considered to require new and additional sequence searches, broadens the claims, and are directed to an invention or inventions that is independent or distinct from the invention originally claimed because claims 22-45 contain recitation of sequence identification numbers 167, 177, 179, and 225 which are not *per se* originally elected sequences. In addition, claims 22-45 contain recitation of clone numbers above and ATCC® deposit numbers 98921 and 98922.

Since, applicant has received an action on the merits for the originally presented invention as directed to sequences 66, 71, 76, 78, 113, 116-118, 123, and 124, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-45

are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03. Claim 21 is pending to which the following grounds of objection and/or rejection are or remain applicable.

35 U.S.C. 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

- "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

- "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

- "Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of

treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the M.P.E.P. at §§ 2107 - 2107.02.

The claimed polynucleotides are not supported by either a specific and substantial asserted utility, or a well established utility. The specification fails to establish by factual data, a utility for the claimed polynucleotides or the encoded proteins. Neither the specification as filed nor any art of record disclose or suggest an activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth below, credibility is not assessed.

The application does not contain description that reasonably conveys to one skilled in the relevant art that the inventor(s), at the time the application was filed, had defined a specific or substantial utility for the claimed invention.

Claim 21 is directed to polynucleotides asserted as encoding the full coding sequences including the signal peptides and/or mature proteins corresponding to the disclosed polynucleotides. Beginning on page 136 and continuing through page 147, some of the polynucleotides of the invention and the encoded proteins are described. No indication exists in this or any other part of the specification which would guide the person wishing to practice the invention such that he would know what the mature forms of the proteins are or which portion(s) constitute signal peptides nor what the function of the peptides are that the DNA encoded. There are no coding sequences disclosed in the specification which have been identified as full-length or mature nor what function the peptides encoded by the polynucleotides would have been. Furthermore, no signal or leader sequences which may be cleaved post-translationally from the proteins have been disclosed. As the claims are currently written, the mature forms of the proteins are described as single, undefined polypeptides, yet no indication has been made in the specification as to what these polypeptides might be, whether or not they differ from the sequences disclosed in the specification or what modifications must be made such that the mature forms would result. While full-length unprocessed proteins may be processed into more than one unique compound, the application does not disclose whether the polynucleotides encoding the instant proteins have only a single precursor form or whether they go through several rounds of signal sequence processing to produce a mature form as is the case with, for example Neurophysin I and II, which are produced from prepropressophysin and prepro-oxyphysin, respectively (Ganong, Figure 14-11), or cholecytokinin-pancreozymin (CCK) which undergoes multiple processing steps such that prepro-CCK is processed into many fragments (Ganong, p. 446). Since neither the signal peptides nor the mature forms of the proteins have been disclosed in the specification, a person skilled in the art would not recognize that Applicants had described a specific and/or substantial utility at the time of filing of the present application as neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established.

As to a specific utility, the current 35 U.S.C. 101/112 Guidelines indicate a utility needs to be *specific* to the subject matter claimed. This contrasts with the *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide (claim 21 among others) whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target (in this instance, there is no apparent target defined in the application). Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease would ordinarily be insufficient absent disclosure of what condition can be diagnosed.

In this instance, pages 10-12 of the response filed 28 December 2000 refers to specification example 64 as support for biological activities of the proteins. The commentary in the response and the example (specification page 134+ and 140+) as directed specifically to SEQ ID NO:76 is unpersuasive as to diagnosis and treatment as page 140+ only indicates that the protein "may" be useful. Maybe, is not the same as is useful nor is it coupled with specifics as to diagnosis nor what modalities of treatment would have been expected to have been conducted and what would have been the expected outcome(s). As to the response citation of the Abraham (2000) reference (exhibit H), the current application was filed prior to the publication of the reference and cannot be relied upon to show utility nor specific utility. Insofar as page 11 of the response refers to examples 25, 26, 53, and 59-61 in regard to discussion of SEQ ID NO:76, examples 25 and 26 do not define nor disclose a use in regard to expression patterns nor expression levels. Neither are tied to any particular disease state/condition nor disclosed as effecting any change to a disease state/condition, especially that for Alzheimer's or other neurodegenerative diseases as argued in applicant's current response. Example 53 does not demonstrate any connection of the polynucleotide of SEQ ID NO: 76 to any hereditary disease or drug response (does not even mention SEQ ID NO: 76 nor any polynucleotide sequence at all). Examples 59 and 60 are directed to antisense oligonucleotides and triple helix probes respectively, but like the previously discussed examples, do not even mention SEQ ID NO: 76 nor any polynucleotide sequence at all nor is there disclosure in these examples of a utility that is tied to any particular disease state/condition nor disclosed as effecting any change to a disease state/condition, especially that for Alzheimer's or other neurodegenerative diseases as argued in applicant's current response. Insofar as example 61 refers to expression of protein in host cells, the protein in the examples is not disclosed to have any function (the assertion regarding Kunitz protease inhibition is not persuasive on the basis of no factual scientific data demonstrating inhibition even where the present response (page 11) refers to selling inhibitors).

In regard to SEQ ID NO: 78, it is noted that the response (page 11) refers to encoding a homologue of a colipase and refers to pages 146-147 as support. These two pages of the specification assert that the polynucleotide encodes a protein that "may" be useful. Maybe, is not the same as is useful nor is it coupled with specifics as to diagnosis nor what modalities of treatment would have been

expected to have been conducted and what would have been the expected outcome(s) especially in the absence of factual/experimental data showing any effect upon disease states/conditions such as hyperlipidemia, hypercholesterolemia, atherosclerosis, cardiovascular disorders, neurodegenertiave disorders and Alzheimer's, dementia, and/or male fertility. None are demonstrated nor supported in the application as filed by disclosure of specific details that result in a specific how to use disclosure. Note the absence of data demonstrating colipase enzymatic function and activity. Additionally, the comments are unpersuasive for the reasons indicated above as to discussion of examples 59-61 as applied to SEQ ID NO: 78.

As to SEQ ID NO:225, the present response (page 11-12) refers to specification page 142 in regard to function as a phospholipid binding protein 2 (PLPB2) as well as refers to U.S. Patent 6,063,767 as indicative of PLPB2 use and again refers to examples 25, 26, 53, and 59-61. For all of the reasons indicated above, the comments are unpersuasive because where the protein may bind phospholipid, it does not define a substantial utility, i.e., a real world use. Page 142 of the present application is indicative that the protein is "thought" to play a role in cell growth/maturation, regulation of sperm maturation, motility/membrane remodeling, signal transduction and/or oxidoreduction reactions – none of which are demonstrated nor pointed to in the response as affecting any of the aforementioned functions. In view of the foregoing, it is readily apparent that the neither the application as filed nor as reconsidered in the response are demonstrative of specific utilities within the current guidelines.

In this application, a substantial utility, is one which defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In this application, it is apparent that with the polynucleotide(s) and the assertion of a function for the encoded proteins, there is no concrete disclosure of methods of treatment for diseases nor concrete (real world) working examples of diagnostics using the polynucleotides nor the encoded proteins. It would appear that the first thing one skilled in the art is forced to do, is to conduct research on what it is the function of the encoded protein. This is criterion (A) of the substantial utility where here, basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved must be done. Thus, the utility is not substantial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claim 21 IS indefinite because it is apparent from the instant application that the SEQ ID NO:s are argued as encoding a a protein. The claim recites "or a sequence complementary thereto". The complementary sequence does not encode the same protein as the coding strand. Thus, it is appears that the claim would require both the coding and complementary strands to encode the same protein. Note that 5' atg encodes Met. The complement is 5'-cat which encodes His.

No claims are allowed.

Applicant's amendment necessitated new/modified grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See M.P.E.P. 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. in the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. in no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 5:50 AM to 11:50 AM on Mondays and from 8:00 AM to 2:00 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of

such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Gabriele E. Bugaisky
Patent Examiner
03/26/01

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